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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LATHROP & GAGE LC
4845 PEARL EAST CIRCLE
SUITE 300
BOULDER, CO 80301

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 04/14/2005

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/773,303

Applicant(s)

PROCTOR, LARRY M.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 56-64 is/are pending in the application.
- 4a) Of the above claim(s) 16-50 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 51, 52 and 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/27/02; 6/2/04</u>
<u>3/15/02; 1/26/04; 7/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed June 2, 2004 has been entered.

Claims 59-64 are newly submitted.

Claim 7 is newly amended.

Claims 1-53 and 56-64 are pending.

Claims 16-50 and 53 are withdrawn.

Claims 1-15, 51, 52 and 56-64 are examined on the merits.

Election/Restrictions

1. This application contains claims 16-50 and 53 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The IDS filed June 2, 2004, which includes references cited on the face of U. S. Patent 5,984,079 and attached at TAB 1 has been considered, and an initialed copy is attached.

The Patent Owner has also provided a PAIRS report at TAB 2, which shows receipt by the Patent Office of IDS materials filed 6-04-2002 and 2-12-2002 in reexamination proceeding 90/005,892, but there are no corresponding entries in the reissue proceeding of the present case 09/773,303. Patent Owner has attached cumulative copies of the forms 1449 at TAB 3.

The Examiner responds that IDS materials filed 2-12-2002 and 6-04-2002 have been considered, as indicated in the last office action. The forms PTO 1449 provided at TAB 3 have

already been considered, as indicated by the initials on the forms. In addition, the seven page PTO 1449, originally submitted on November 15, 2002, is initialed, and a copy is attached.

Please note that the citations at No. 14, 17, 65 and 98 have been considered, but have been lined out, given that no dates are provided. Furthermore, the one page PTO 1449 at TAB 3 that is not initialed and has as item 1 "Pod-Ner's Response to Defendants' Motion to Compel" is a duplicate form. This form was initialed on August 26, 2003 and is part of the file. A copy is provided to Patent Owner attached to the present office action.

Oath/Declaration

The replacement Declaration filed June 2, 2004 has been entered and is accepted.

Claim Objections

The claim objections set forth in the office action of December 2, 2003 are withdrawn in view of the amendment filed June 2, 2004.

Claim Rejections - 35 USC § 112

2. Claims 59 and 62, and claims 60, 61, 63 and 64 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly submitted claim 59 recites "wherein the yellow color plotted as a distribution in the population of the seed of sufficient

number for purposes of ATCC deposit has a peak occurrence ranging”; and newly submitted claim 62 recites “as evidenced by a substantially uniform yellow color of the seed coat, wherein the substantially uniform yellow color plotted as a distribution in a population of the seed of sufficient number for purposes of ATCC deposit has a peak occurrence ranging”. However, these phrases were not present in the specification as originally filed, and the subject matter now claimed was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

3. Claims 1-15, 51, 52 and 56-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action of September 25, 2002.

4. Patent Owner’s arguments filed June 2, 2004 have been fully considered but are not persuasive. Patent Owner questions the nature of the rejection. Patent Owner questions “whether the rejection is generically based on written description, or particularly with respect to possession” (at page 12, lines 10-11).

The Examiner points to *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d at 969 where it states:

“Application of the written description requirement, however, is not subsumed by the ‘possession’ inquiry. A showing of ‘possession’ is ancillary to the statutory mandate that

‘[t]he specification shall contain a written description of the invention,’ and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention.” The specification must teach the invention by describing it.

Patent Owner argues that they have shown possession of the claimed invention by “an exacting discussion of plant morphology and selection processes, together with an ATCC deposit of the germplasm” (at page 13, lines 4-5). Patent Owner goes on to state that the Office has characterized the ATCC deposit of record too narrowly, because this biological material can be used to develop a number of different cultivars, pointing to the Abstract and the patent issued from the parent application, US 5,894,079 at column 6, lines 9-12. Patent Owner further asserts that *Enzo Biochem Inc. v. Gen-Probe Inc.*, USPQ2d 1609 (Fed. Cir. 2002) determined that “a deposit of genetic material may suffice to describe that material”. In addition, Patent Owner argues that a description of properties inherent to the product do not have to be disclosed in the original specification, citing *In re Nathan*, 328 F.2d 1005, 1008-1009, 140 USPQ 601, 604 (CCPA 1964) and *Kennecott Corp. v. Kyocera Int’l, Inc.*, 835 F.2d 1419, 1421, (Fed. Cir. 1987). Therefore, Patent Owner concludes that claims 59-64 meet the written description requirement given that they merely describe inherent properties of the ATCC deposit.

In addition, Patent Owner strongly disagrees with statements made by the Office that assert that statements made of record by the Patent Owner conflict with statements made in the patent disclosure. Patent Owner argues that the Office has asserted that Enola bean is described as a “cultivar” in the specification, and that this is understood to mean “a genotypically and phenotypically homogeneous population of plants”. Patent Owner states that the “Office is using

an arbitrary concept of genetic and phenotypic uniqueness or homogeneity . . . to define a cultivar and to assert for legal purpose for making a seed deposit" (at page 14, the second paragraph of the response), and that the Office must provide a reference to support both positions. Patent Owner asserts that the word "cultivar" does not appear in the claims, and that the dictionary definition of "cultivar" does not require genotypic and phenotypic homogeneity, as shown in the evidence provided at TAB 5. Patent Owner points to the Declaration of Gil Waibel as showing that Enola has been uniform and stable in 1996, 2001 and 2002.

The Examiner maintains that the Declaration of Gil Waibel provides evidence of the nonuniformity of the deposited seeds. In addition, while "cultivar" is not recited in the claims, the word "cultivar" is known in the art to mean a "cultivated variety" (see the website victoryseeds.com/information/glossary.html, printout from April 1, 2005 is attached). A cultivar is also known to be a plant that "has been selected for some feature that distinguishes it from the species from which it is selected" (see the website usna.usda.gov/Gardens/glossary.html, printout from April 1, 2005 is attached). In the present case, Patent Owner has not identified what feature or features distinguish the claimed seeds from other known *Phaseolus vulgaris* seeds.

Patent Owner then asserts that the Office states both that variant traits in Enola have not been observed, and that there is too much genetic variation, thus contradicting itself. Yet, the Patent Owner will not state, at this time, whether there is or is not wide ranging genetic variation in the Enola cultivar. Patent Owner asserts that they refer to Enola as a cultivar because it is "persistent under cultivation" and because it is "distinguished from other plants by common characteristics or qualities" (at the sentence bridging pages 15-16), which are stable and are described in the specification. Patent Owner states that it is well documented that individuals

within a cultivar can have a unique genetic makeup, though the members of the cultivar share uniform and stable traits or phenotypes that persist under cultivation.

The Examiner maintains that Patent Owner has not set forth what the uniform and stable characteristics are that distinguish the claimed seeds from other known *Phaseolus vulgaris* seeds. Furthermore, see at column 4, line 60, where it states "The field bean cultivar Enola will not be described". Patent Owner has not described the claimed seeds and plants.

Patent Owner states that the ATCC deposit is a "genus of cultivar comprising individual species" (page 16, the last full paragraph). The Examiner maintains that this statement makes no sense in the context of the meaning of "cultivar", as stated above. Patent Owner argues that the Office is requiring exact copies with no genetic variation, while the art teaches selecting plants for desired traits, with breeders using "a milieu of genetic material . . . to reinforce desired traits or phenotypes" (page 17, second paragraph) and stating that using the Office's definition that it would be impossible to improve a cultivar by the process of continuing selection. The Examiner maintains that Patent Owner is describing the process for identifying a desired cultivar, not the resulting variety. The Office is not requiring exact copies. The Examiner maintains that Patent Owner has not described a variety that has specific uniform and stable characteristics that distinguish the claimed seeds from other known *Phaseolus vulgaris* seeds. Patent Owner has argued that the seeds of the deposit comprise a variety of different characteristics.

Patent Owner asserts that the differences pointed out by the Office are small variations relative to the stable and uniform traits described. The Examiner maintains that Patent Owner has not set forth what the stable and uniform traits are that distinguish claimed seeds from other known *Phaseolus vulgaris* seeds.

The Patent Owner points to the Declaration of Gil Waibel as showing comparative differences that would be expected from a uniform and stable cultivar over the course of several crop years. Patent Owner asserts that the Office quoted a section of the specification as showing that Enola does not have variant traits, but that the passage was taken out of context (page 18). Patent Owner argued in the response filed March 25, 2003 at page 6, where it states “the Patent Owner ‘describes’ a single cultivar ‘Enola’ (seed deposited as ATCC Accession Number 209549). However, the seeds deposited with the ATCC are not the seeds of a single genetic entity. Rather the seeds represent a variety of genetic entities, with a range of sizes shapes and colors, both seed coat and hilar ring. Furthermore, the growout was conducted using seeds from the same source as the ATCC seeds, the plants, pods and seeds displayed a comparable diversity of characteristics” and that the Declaration of Polly Proctor confirmed the genetic diversity. The Examiner maintains that Patent Owner has provided evidence that the deposited seeds have many traits that are not stable and uniform. Patent Owner has not identified what trait or traits are uniform and stable that distinguish the claimed seeds from others of the same species.

Patent owner argues that the Office misapplies *University of California* as being broadly applicable to any type of invention, and not just to cDNA. Patent Owner finds it necessary “to educate the Office as to the current status of that case”. Patent Owner asserts that *Moba, B. V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320, 66 USPQ2d 1429, 1438-1439 (Fed. Cir. 2003) establishes a new test for written description that takes into account information from deposits of “sequences, subsequences, mutated variants and mixtures” rather than specific defined DNA sequence in the specification.

The Examiner maintains that the Federal Circuit has recently held that the written description standard applies to compounds other than DNA. See *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925, 69 USPQ2d 1886, 1893 (Fed. Cir. 2004), where it states that “the statute applies to all types of inventions”. The *Rochester* court also held that written description applies to methods as well as products, where it states: “Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.” *Id.* At 926, 69 USPQ2d at 1894.

Patent Owner argues that the “possession” test is met by the deposit of seeds and is supported by the Declaration of Gil Waibel, which sets forth the inherent properties (page 21), also that possession is met when the specification sets forth the selectable traits and other morphological traits of Enola (page 24). The Examiner maintains that the claimed invention is not described, and that Patent Owner’s arguments suggest that by the deposit, Patent Owner intends to claim a large genus of genotypes and phenotypes that have not been described in the specification.

Patent Owner asserts that the claims drawn to seeds having a particular yellow color do not recite functional language. The Examiner maintains that seed color is the functional expression of the structural gene coding for this characteristic. Patent Owner states that plant breeders select on the basis of phenotypes not genetic sequences. The Examiner maintains that phenotypes are the functional expression of the genetic sequences comprised in a plant.

Patent Owner asserts that it was improper for the Office not to consider the Bassett reference based on the argument that it was presented to rebut the rejection based on enablement, while it is evidence to show the advanced state of breeder selection art. Patent Owner states that "Bassett acknowledges use or comparison of Enola germplasm, and is provided to show the level of skill". Patent Owner argues that the Office has not placed the written description rejection in the context of the related art, so arguing that there is no *prima facie* case, and not Patent Owner's burden to provide evidence to rebut the case. Also, asserting that the Patent Owner has rebutted the case under the *University of California*, and that *Lockwood* and *Moba* determine that the written description rejection must be determined from the ordinary skill in the art, including the nature of the art and the level of skill in the art with regard to possession. Patent Owner submits a Genetics Committee List of Genes for *Phaseolus vulgaris L.* to exemplify this and indicate the advanced state of the art, "where it has compiled a comprehensive list of genes and rules for the breeder use of such genes" (page 27). Patent Owner goes on to discuss that the beans of the invention may be used in breeding to produce more highly desirable beans.

The Examiner maintains that Patent Owner is arguing enablement, not written description. In addition, the Examiner questions the assertion that the art of bean breeding is so advanced that a comprehensive list of genes and rules for the use of said genes has been compiled. If this were true, then all bean cultivars with varied traits would be either known or obvious in view of the state of the art.

5. Claims 1-15, 51, 52 and 56-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action of December 2, 2003.

6. Applicant's arguments filed June 2, 2004 have been fully considered but they are not persuasive. Patent Owner asserts that the Office incorrectly views the seed deposit as a reproducible means of producing the claimed plant, which the Office states is not enabled by a heterogeneous mix of seeds in the deposit. Patent Owner argues that the Declaration of Gil Waibel shows that Enola stably produces the disclosed phenotypes, asserting that the Office "assumes that genetic variation within a cultivar necessarily results in non-uniform phenotypes." The Examiner responds that it is Patent Owner's own words in the response of March 25, 2003 that describe the phenotypic variation of the deposited seed. The Declaration of Gil Waibel describes variation in Enola, see beak orientation (#26, #35), pod color (#31). Primary color of seed coat (#42) asserts that "most" of the seed was in the color range Munsell 5Y 8.5/4 to 7.5Y 8/8, which is different from the seed color range claimed and disclosed in the specification, seed weight (#48) is quite different for Enola in the two studies cited.

Patent Owner asserts that the deposit is required to describe how to make and use the invention in a reproducible manner, but not for the production of "a genotypically and phenotypically unique plant that cannot be recreated based on a patent disclosure". Patent Owner states that Enola is reproducible because it exhibits stability and uniformity with regard to the selected traits and other traits that are shown and described in the specification, and as confirmed by the declaration of Gil Waibel. The Examiner maintains that Patent Owner has not

identified any selected traits that are stable and uniform and that differentiate that claimed seeds and plants from other known *Phaseolus vulgaris* seeds and plants.

In addition, Patent Owner argues that the specification provides guidance for making other cultivars by crossing with other cultivars and selecting for traits, such as: segregated color, small leaves, good adherence of the pod to branches, resistance to pod shattering and greater than average yield, among numerous other traits described in Example 1, and the ATCC deposit provides the needed germplasm. Patent Owner asserts that “the art does not view selectable traits as being linked to any one cultivar and recognizes that such traits may be crossed into other populations”. Patent Owner argues that it would not require undue experimentation for one of ordinary skill in the art to practice the invention in view of the deposited germplasm, wherein “the art views this as germplasm for a selectable and crossable trait of *Phaseolus vulgaris*”. Again, the Examiner maintains that Patent Owner and the Declaration of Gil Waibel both have described the deposited seeds as varied in phenotype, as stated above. Patent Owner has not provided guidance with regard to how one skilled in the art would select from the heterogeneous seeds that are deposited to identify individuals to cross with other cultivars, and what traits the resultant plants would be selected for. The Examiner maintains that it would require undue experimentation by one skilled in the art to practice the claimed invention, in view of the heterogeneity of the seeds of the deposit, and for the reasons already of record. As stated in the last office action, the purpose of deposit of seed is to provide a reproducible means of making a unique plant that cannot be recreated based on a patent disclosure. Therefore, the deposit of a phenotypically varied population of seeds does not allow one of skill in the art to reproduce the

same invention. Each sample of seed obtained from the ATCC would consist of a different mixture of seed and result in a different heterogeneous population of plants.

7. Patent Owner states that the disclosure teaches how to select for the color feature of the claimed bean, and that the Bassett reference teaches “a sufficient level of skill to duplicate these results from other cultivars, e.g., by crossing and selecting for color”, and that Bassett also exemplifies the high level of skill in the art with regard to breeding for seed coat color. Patent Owner also argues that the breadth of the claims is not undue, given that the deposited germplasm may be crossed to other populations and improved by continued selection. Patent Owner argues that while the Bassett article does not follow the teachings of the disclosure, that Bassett identifies Wagenaar as a potential parent of Enola and proposes a new SGY trait that is indicative of the Enola seed coat color. The Examiner maintains that Patent Owner’s assertion that Bassett provides evidence for enablement of the claimed invention is not persuasive, given that the specification must provide the support to enable the claimed invention. The specification does not disclose an SGY trait for use in identifying seeds having Enola seed coat color. Furthermore, in arguments at page 36 of the response, Patent Owner points to the Declaration of Paul Gepts, which teaches the use of RFLP to identify a wholly different cultivar as the closest parent. The Examiner maintains that the response of Patent Owner points to a high degree of uncertainty with regard to the parentage of the Enola bean, which supports the assertion that the claimed invention is not enabled.

8. Claims 1-7, and 57 remain rejected and newly submitted claims 59-64 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the last office action.

Claim 1, and claims dependent thereon, remain indefinite in view of Patent Owner's statement that the seeds deposited with the ATCC are not seeds of a genetic entity.

9. Patent Owner's arguments filed June 2, 2004 have been fully considered but they are not persuasive. Patent Owner asserts that they do not agree or disagree that the cultivar contains a uniform genotype. The Examiner maintains that by making this statement, Patent Owner has admitted that the metes and bounds of the claimed invention are not clear. Apparently, Patent Owner does not know if the cultivar has a uniform genotype, or not, although Patent Owner asserted in the prior response that the seeds, in fact, differ in color, shape and size.

10. Patent Owner then states that there is evidence of genetic diversity within the Enola cultivar, but that the genetic diversity is not linked to diversity of phenotype or trait, and that "Enola expresses the selected characteristic traits uniformly and stably" (at page 34 of the response), and that the Declaration of Gil Waibel shows this. Patent Owner argues that one would be able to determine what materials infringe by a comparison of the detailed disclosure of plant morphology, which is reflected in the "unambiguous wording in the claims" (at page 34 of the response). The Examiner maintains that it is unclear what the uniform and stable selected characteristics in the claimed plants and seeds are, given that Patent Owner has stated on the record that the seeds are heterogeneous in phenotype and there is also evidence of genetic diversity in the seeds that are deposited as ATCC Accession number 209549. It is clear that the specification does not define the full range of seed phenotypes and genotypes that are comprised

in the deposit, such that one skilled in the art would be able to determine what materials would infringe the claim.

11. Patent Owner further remarks that with regard to the deposited seeds, additional studies could be done to show similarities with the overall cultivar. This statement is not understood. The Examiner maintains that if additional studies are needed to identify similarities, then it is clear that the properties of the deposited seeds are not clearly defined. Patent Owner then requests withdrawal of the enablement rejection. However, the rejection being argued is that of indefiniteness.

12. Claim 10 remains indefinite for lack of proper antecedent basis, as stated in the last office action. Patent Owner has not responded to this rejection, so the rejection is maintained.

13. Claim 57, at line 1, the phrase "said seed from the middle of a pod" lacks proper antecedent basis. It is recommended that the phrase be amended to recite --said seed is from the middle of a pod and is cuboid in shape--, as stated in the last office action. Patent Owner has not responded to this rejection, so the rejection is maintained.

14. Newly submitted claim 59, and claims 60 and 61 dependent thereon, are indefinite in the recitation of "wherein the yellow color plotted as a distribution in the population of the seed of sufficient number for purposes of ATCC deposit has a peak occurrence ranging"

Newly submitted claim 62, and claims 63 and 64 dependent thereon is indefinite in the recitation of "as evidenced by a substantially uniform yellow color of the seed coat, wherein the

substantially uniform yellow color plotted as a distribution in a population of the seed of sufficient number for purposes of ATCC deposit has a peak occurrence ranging”.

Claim Rejections - 35 USC § 102/103

15. Claims 1-15, 51, 52 and 56-64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of CIAT G13 094, G02 400, G22 215, G22 227, 622 230, G11 891 or Kaplan (Guitarrero Cave, p. 146, 1980), or Hernandez-Xolocotzi et al (Seminar Series 2E, CIAT, p. 253-258, 1973) or Voysest (Varieties of Beans in Latin America, CIAT, p. 47-50, 1983) or Gepts (The Genetic Resources of Phaseolus Beans, p. 602, 1988) or Azufrado Peruano 87 (Secretaria de Agricultura Y Recursos Hidraulicos; Solicitud de Incripcion en el Registro Nacional de Variedades de Plantas, Registration No. FRI-150288-042, September 25, 1987 at No. 52 an 53, in the IDS filed November 15, 2002) for the reasons of record set forth in the prior office actions, and in view of the documents filed June 2, 2004.

16. Patent Owner's arguments filed June 2, 2004 have been fully considered but they are not persuasive. Patent Owner asserts that the beans that the Office is requiring Patent Owner to test are unavailable to them, and it is a burden for them as a small entity of only three employees to carry out the required testing. Patent Owner states that they have obtained some of the beans for testing and that the test results are provided in the attached Declaration of Polly Proctor (TAB 9). Patent Owner argues that the test results are not even close, and that the Declaration of Gil Waibel shows that different environmental conditions spanning several years did not produce the kind of variation that the Office speculated might occur. Patent Owner states that the Enola seed coloration did not vary appreciably.

17. The Examiner maintains that the rejection is proper in view of the evidence provided in the Polly Proctor Declaration. The disclosure describes characteristics of the seeds of the deposit, and claims 8, 13, 51 and 59 specify that the seed color is yellow from about 7.5Y 8.5/4 to about 7.5Y 8.5/6 in the *Munsell Book of Color*. The Declaration of Polly Proctor provides charts indicating that by her observations all of the cultivars had some variation of seed color. The seed coats of G13094, include the Munsell colors 7.5Y 8/6 and 7.5Y 8/8; G22215, includes seeds having seed coats of 7.5Y 8/6 and 7.5Y 8.5/8; G22227, includes seeds having seed coats of 7.5Y 8/4, 7.5 8/6 and 7.5Y 8/8; and G22230, includes seeds having seed coats of 7.5Y 8/6, 7.5Y 8/8 and 7.5Y 8.5/10. These color designations are all based on Polly Proctor's determination and the declaration states that they have been done in a uniform way and under natural light.

The specification describes characteristics of the seeds of the deposit and claims 10, 15 and 64 further specify that the hilar ring color is from about 2.5Y 9/4 to about 2.5Y 9/6. The hilar rings of G22215 include the Munsell colors 2.5Y 7/6, 2.5Y 8.5/6 and 2.5Y/8.8; G22227 has hilar rings with colors including 2.5Y 8.5/4 and 2.5Y 8.5/6; and G22230 has hilar rings with colors including 2.5Y 8.5/6 and 2.5Y 8/6. These color designations are all based on Polly Proctor's determination and the declaration states that they have been done in a uniform way and under natural light. Also, with regard to the information provided on PI 282060, PI 312090 and PI 208777, it could not be evaluated, given that the table does not specify what the colors in the table refer to. Are these colors of the seed coat or the hilar ring?

Each of the color designations set forth in the Polly Proctor Declaration fall within the range set forth in the claims, given that the claims read on any *Phaseolus vulgaris* seeds having seed coat color "about 7.5Y 8.5/4 to about 7.5Y 8.5/6" or having hilar ring color from about

2.5Y 9/4 to about 2.5Y 9/6. Given the use of “about” in the claims, the claims are clearly anticipated by prior art seeds as demonstrated by the Declaration of Proctor.

Furthermore, the Declaration of Proctor does not provide information with regard to the seed coat color of Enola seed in a side-by-side comparison with the prior art seeds. The Declaration of Polly Proctor states that the color analysis was done in natural light. However, natural light is highly variable and the determination of color is subjective. The website: hyperphysics.phy-astr.gsu.edu/hbase/vision/specol.html (March 30, 2005 printout is attached) teaches that the Munsell color measurement system is subjective and that it is to be used for comparison of color “with adjacent samples based upon equal perceived differences in color”. Therefore, while the Proctor Declaration identifies seed coat color for the prior art seeds, this determination was a personal determination of Polly Proctor based on subjective criteria, and not supported by a side-by-side comparison with the seeds of the deposit under the same conditions of natural light. In addition, the Polly Proctor Declaration is by a person that is related to the inventor. The Declaration of Proctor is not persuasive in overcoming the rejection for all of the reasons set forth above.

In addition, Patent Owner has asserted previously that the seeds of the deposit, vary in color, size and shape. Therefore, it remains uncertain what the characteristics of the claimed seeds are, and how the claimed seeds differ from any of the prior art seeds. In fact, in the response of March 25, 2003 Patent Owner describes the phenotypic variation of the deposited seed, and the Declaration of Gil Waibel describes variation in Enola, see beak orientation (#26, #35), pod color (#31). Primary color of seed coat (#42) and asserts that “most” of the seed was in the color range Munsell 5Y 8.5/4 to 7.5Y 8/8. In view of the broad range of color identified

by Waibel, it remains clear that the prior art cultivars anticipate the claims, as made evident by the color designations set forth in the Declaration of Polly Proctor.

Patent Owner also argues that Bassett has documented that Enola has a new selectable trait, identified as *gy* or *SGY*, and states that this confirms the novelty and nonobviousness of Enola bean. Patent Owner then points to the Declaration of Paul Gepts, which teaches the use of RFLP to identify a wholly different cultivar as the closest parent. While, Patent Owner argues at page 33 of the response that Bassett identifies Wagenaar as a potential parent of Enola and proposes a new *SGY* trait that is indicative of the Enola seed coat color.

The Examiner maintains that Patent Owner cannot rely on post-filing date experimentation to support the claim of novelty and nonobviousness of the claimed invention. The specification does not teach a *gy* or *SGY* selectable trait or claim this as a distinguishing feature of the claimed invention. Furthermore, given the differing results of Bassett and Gepts with regard to identifying the parentage of Enola, Patent Owner's response suggests that the genetic makeup of Enola appears to be in question. However, a recent publication suggests otherwise. Pallottini et al (Crop Science 44: 968-977, 2004) have done a detailed study of AFLP fingerprints of 24 cultivars with yellow seeds. The results of their study indicate that the claimed Enola bean has an identical fingerprint to yellow-seeded beans from Mexico and is most similar to Azufrado Peruano 87. Pallottini et al teach that the most likely origin of Enola is by direct selection within pre-existing yellow bean cultivars, and most likely Azufrado Peruano 87 (see the abstract, the second column of page 972, Figures 2 and 3, and the last paragraph of page 976, for example).

18. Patent Owner asserts that it is an unreasonable burden for them to test all of the cultivars that are cited as prior art, and that there is no reasonable basis for this requirement. Patent Owner argues that the PTO has not provided a sound basis for believing that the products claimed are the same as those taught in the prior art. Patent Owner states that all of the beans that were found to be obtainable from repositories have been tested. Patent Owner states that Kaplan, Hernandez, Voysest or Gepts have not been tested. Patent Owner requests that the burden be lifted and the rejection be withdrawn.

The Examiner maintains the rejection over all of the prior art beans that are cited in the rejection, given that the claimed bean seeds are clearly anticipated, as evidenced by the Polly Proctor Declaration, and given the uncertainty with regard to the characteristics of the claimed bean seeds, and further given the subjective nature of color determination under conditions of natural light. Furthermore, the yellow beans taught by Voysest are Azufrado Peruano that were used in the testing carried out by Pallottini et al. It seems that the research group of Pallottini et al did not have difficulty in obtaining these and 23 other yellow bean cultivars. Furthermore, Patent Owner has provided at TAB 11 documents pertaining to court proceedings involving the Enola bean patent. In the Brief In Support of Defendant's Motion to Compel Plaintiff to Produce Documents of August 21, 2002 (Cite No. 100), it states that Dr. Pfeiffer testified that "Azufrado Peruano 87 to be the same basic thing as the Enola"(page 8, lines 1-2), and that "Azufrado Peruano 87 is indistinguishable from the Enola (at page 8, lines 13-14), and that in a memo to Patent Owner in August 27, 1997, Dr. Pfeiffer wrote "It will not take someone schooled/learned in beans long to find out where the Enola came from originally and that what we are calling

Enola is actually Peruano 87". Patent Owner's argument that the beans were not obtainable is not persuasive. The rejection is deemed proper and is maintained for the reasons of record.

19. Finally, the Examiner does not view remarks with regard to the credibility of an external organization to have any relevance in the prosecution of the present application. The application is evaluated based on the facts provided in the case.

Information Assessment

The Examiner maintains that Requirement for Information Under 37 C.F.R. 1.105, as set forth in the last office action.

Patent Owner states that a full response to the request for information has been filed in the form of the Declaration of Larry Proctor (TAB 10) and associated documents including IDS (TAB 11), in addition to the information already of record.

The Examiner maintains that Patent Owner has not been fully responsive to the Requirement for Information Under 37 C.F.R. 1.105 given that the papers provided point to a search done by Attorney Flores with regard to existing yellow beans in 1993, which has not been provided. In the Brief "In Support of Defendant's Motion to Compel Plaintiff to Produce Documents of August 21, 2002 (Cite No. 100)", it states that a search was done in the U.S. and Mexican Patent Office with regard to two yellow bean varieties (at page 3). The papers provided by Patent Owner also point to conflicting information with regard to how Patent Owner derived the claimed yellow beans. The papers provided indicate that Patent Owner now asserts in court documents that the manner in which the Enola bean was derived is different from what is taught in the present specification. See Pod-Ners Response to Defendant's Motion (Cite No. 101) at

page 29, where it states that Patent Owner began the development of Enola bean in 1991, instead of in 1994, as it stated in the issued patent and in the PVP Certificate.

The papers provided by Patent Owner in the form of the Deposition of Brunner suggest that the claimed Enola bean is not different than other yellow beans that have been grown and sold in the U.S. for many years (see pp. 199-200). In addition, statements by Pfeiffer in the briefs filed assert that he and Patent Owner were both aware that the Enola bean was obtained by selection of plants grown from Azufrado Peruana 87 seeds, as stated above. However, the Patent Owner did not provide this information to the PTO or in the application for Plant Variety Protection Certificate. The Examiner maintains that the Requirement for Information, as set forth in the previous office action, has not been met for the reasons set forth above. Patent Owner is required to provide any information available regarding the sale within the ambit of your control or that of a third party or the public use in the United States of the field bean seeds originally obtained in Mexico. Because the inventor purchased the field bean seeds in Mexico and brought them to the United States, it is reasonable to expect that Patent Owner or assignee can readily obtain information regarding the public use or sale of said seeds in the United States at the time of the original purchase and/or prior to the filing date of the instant patent.

No claims are allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

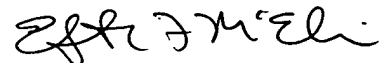
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Elizabeth F. McElwain, Ph.D.

Primary Examiner

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